

EMERGENT

Humanigen and Emergent BioSolutions Announce Contract Development and Manufacturing Agreement for Phase 3 COVID-19 Therapeutic Candidate Lenzilumab™

January 25, 2021

GAITHERSBURG, MD. and BURLINGAME, CA. – Jan. 25, 2021 —[Emergent BioSolutions Inc.](#) (NYSE:EBS) (Emergent) and [Humanigen, Inc.](#) (NASDAQ:HGEN) (Humanigen) today announced that they have entered into a contract development and manufacturing (CDMO) services agreement to accelerate the drug product manufacturing of lenzilumab™, an anti-human granulocyte macrophage-colony stimulating factor (GM-CSF) monoclonal antibody designed to prevent and treat an immune hyper-response called “cytokine storm.” Emergent will provide access to manufacturing capacity reserved for and provided by the U.S. government under Humanigen’s Cooperative Research and Development Agreement (CRADA) with the Department of Defense’s (DOD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) in collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services. Lenzilumab is currently in a Phase 3 clinical trial evaluating patients hospitalized with COVID-19. Humanigen intends to file for emergency use authorization (EUA) in the first quarter of 2021.

Under the terms of the agreement, Emergent will provide its integrated CDMO services for the manufacturing of drug product batches to support Humanigen’s efforts to increase supply of lenzilumab in anticipation of a potential EUA beginning in the first quarter of 2021, including utilization of a new state-of-the-art flex fill line at Emergent’s Baltimore, MD (Camden) drug product manufacturing facility. This newly expanded facility was built to provide increased capacity and flexibility to support companies in need of clinical and commercial manufacturing capabilities. The parties intend to negotiate a commercial manufacturing services agreement that could include future fill batches for a biologics license application (BLA).

“As we continue to advance lenzilumab for patients hospitalized with COVID-19, we are executing on plans to ensure that we have the necessary support for the next phase of our growth. Partnering with leading CDMOs like Emergent BioSolutions to help us build out our manufacturing capacity is a cornerstone to that strategy,” said Cameron Durrant, MD, MBA, chief executive officer of Humanigen. “The impact of BARDA’s support through our CRADA and its public-private CDMO partnership with Emergent is vital to our progress and bringing innovative solutions for patients with COVID-19.”

For Emergent, this agreement follows and is in addition to the landmark public-private CDMO partnership between Emergent and BARDA, announced in June 2020, to pave the way for high-priority innovators leveraging reserved capacity at their Drug Substance and Drug Product facilities.

“Drug product manufacturing is a hallmark capability of our CDMO services, and we stand ready to harness our expertise to advance lenzilumab, Humanigen’s COVID-19 therapeutic candidate,” said Syed T. Husain, senior vice president and CDMO business unit head at Emergent BioSolutions. “Every second counts in the fight against COVID-19, and we are proud that Humanigen trusts us to rapidly deploy our clinical-to-commercial manufacturing operations to fulfill the urgent need for COVID-19 therapeutic options.”

This agreement marks Emergent’s seventh CDMO collaboration with government and industry partners working to deliver COVID-19 vaccine and therapeutic solutions.

About Emergent BioSolutions

Emergent BioSolutions is a global life sciences company whose mission is to protect and enhance life. Through Emergent’s specialty products and contract development and manufacturing services, Emergent is dedicated to providing solutions that address public health threats. Through social responsibility, Emergent aims to build healthier and safer communities. Emergent aspires to deliver peace of mind to its patients and customers so they can focus on what’s most important in their lives. In working together, Emergent envisions protecting or enhancing 1 billion lives by 2030. For additional information, visit Emergent’s [website](#) and follow Emergent on [LinkedIn](#), [Twitter](#) and [Instagram](#).

About Humanigen, Inc.

Humanigen, Inc. is developing its portfolio of clinical and pre-clinical therapies for the treatment of cancers and infectious diseases via its novel, cutting-edge GM-CSF neutralization and gene-knockout platforms. Humanigen believes that its GM-CSF neutralization and gene-editing platform technologies have the potential to reduce the inflammatory cascade associated with coronavirus infection. Humanigen’s immediate focus is to prevent or minimize the cytokine release syndrome that precedes severe lung dysfunction and ARDS in serious cases of SARS-CoV-2 infection. Humanigen is also focused on creating next-generation combinatory gene-edited CAR-T therapies using strategies to improve efficacy while employing GM-CSF gene knockout technologies to control toxicity. In addition, Humanigen is developing its own portfolio of proprietary first-in-class EphA3-CAR-T for various solid cancers and EMR1-CAR-T for various eosinophilic disorders. Humanigen is also exploring the effectiveness of its GM-CSF neutralization technologies (either through the use of lenzilumab as a neutralizing antibody or through GM-CSF gene knockout) in combination with other CAR-T, bispecific or natural killer (NK) T cell engaging immunotherapy treatments to break the efficacy/toxicity linkage, including to prevent and/or treat graft-versus-host disease (GvHD) in patients undergoing allogeneic hematopoietic stem cell transplantation (HSCT). Additionally, Humanigen and Kite, a Gilead Company, are evaluating lenzilumab in combination with Yescarta® (axicabtagene ciloleucel) in patients with relapsed or refractory large B-cell lymphoma in a clinical collaboration. For more information, visit [www.humanigen.com](#) and follow Humanigen on [LinkedIn](#), [Twitter](#) and [Facebook](#).

Emergent BioSolutions Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding Emergent’s ability to advance potential solutions to combat coronavirus disease as well as the anticipated production of the lenzilumab™ Phase 3 COVID-19 experimental therapeutic candidate at expected levels in the expected timeframe, as well as the potential negotiation of a future commercial manufacturing services agreement that could include fill batches for a BLA, are forward-looking statements. These forward-looking statements are based on current intentions, beliefs and expectations regarding future events. Emergent cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, Emergent does not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause Emergent's actual results to differ materially from those indicated by such forward-looking statements, including the success of the planned development program; the timing of and ability to obtain and maintain regulatory approvals or authorization for emergency or broader patient use for the product candidate; and Emergent's commercialization, marketing and manufacturing capabilities. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in Emergent's periodic reports filed with the SEC, when evaluating Emergent's forward-looking statements.

Humanigen Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although Humanigen management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual events or results may differ materially from those contained in the forward-looking statements. Words such as "will," "expect," "intend," "plan," "potential," "possible," "goals," "accelerate," "continue," and similar expressions identify forward-looking statements, including, without limitation, statements regarding the use of lenzilumab to treat patients hospitalized with COVID-19, Humanigen's expectations regarding the timeline to file for and obtain EUA, as well as a potential BLA filing, statements regarding Humanigen's ability to attain necessary manufacturing support from CDMOs, the potential for an expanded manufacturing services relationship with Emergent, and statements regarding Humanigen's beliefs relating to any of the other technologies in Humanigen's current pipeline. These forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the risks inherent in Humanigen's lack of profitability and need for additional capital to grow Humanigen's business; Humanigen's dependence on partners to further the development of Humanigen's product candidates; the uncertainties inherent in the development, attainment of the requisite regulatory approvals or authorization for emergency or broader patient use for the product candidate and launch of any new pharmaceutical product; the outcome of pending or future litigation; and the various risks and uncertainties described in the "Risk Factors" sections and elsewhere in the Humanigen's periodic and other filings with the Securities and Exchange Commission.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You should not place undue reliance on any forward-looking statements, which speak only as of the date of this release. Humanigen undertakes no obligation to revise or update any forward-looking statements made in this press release to reflect events or circumstances after the date hereof or to reflect new information or the occurrence of unanticipated events, except as required by law.

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Emergent BioSolutions Contacts:

Investors:

Robert G. Burrows
Vice President, Investor Relations
240-631-3280
burrowsr@ebsi.com

Media:

Miko B. Neri
Senior Director, Global Communications & Public Affairs
240-631-3392
nerim@ebsi.com

Humanigen Contacts:

Investors:

Alan Lada
Solebury Trout
856-313-8206
alada@troutgroup.com

Media:

Cammy Duong
Westwicke, an ICR company
203-682-8380
cammy.duong@westwicke.com

